## REMARKS

Claims 1-5 are pending.

**Rejections Under 35 U.S.C. §102**

Claims 1-2 and 4-5 were rejected under 35 U.S.C. §102(a) on the assertion that they are anticipated by Lal et al. (WO 00/00610, published 1/6/2000). The Examiner asserts that the priority of the instant application has been amended such that the earliest effective filing date is 8/24/2000, which is after the publication date of Lal et al. Claims 1-2 and 4-5 were also rejected under 35 U.S.C. §102(e) on the assertion that they are anticipated by Walker et al. (U.S. Patent 6,277,57481, filed 4/9/1999).

According to the Examiner, the Declaration submitted October 11, 2005 under 37 CFR 1.131 is ineffective to overcome the applied references because the evidence submitted is insufficient to establish a conception of the invention or reduction to practice prior to the effective dates of the cited references. In particular, the Examiner asserts that the Declaration is insufficient because it would have been impossible to envisage the expression level of DNA59211-1450 in normal kidney compared to kidney tumor prior to the experiment performed on June 13, 2000, in which primers were used to determine the expression level of DNA59211-1450 (SEQ ID NO: 49 encoding the claimed polypeptide SEQ ID NO: 50) in various tumor samples. According to the Examiner, there must be a contemporaneous recognition and appreciation of the invention for there to be conception. In support of his position, the Examiner cites *Silvestri v. Grant*, 496 F.2d 593, 596, 181 USPQ 706. 708 (CCPA 1974) and *Bosies v. Benedict*, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed. Cir. 1994).

I. U.S. Provisional Application Serial No. 60/088740 Establishes Conception Prior to the Effective Dates of Lal and Walker

With respect to the Examiner's position that the priority of the instant application has been amended such that the earliest effective filing date is 8/24/2000, Applicants note that 37 C.F.R. 1.131 and M.P.E.P. §715 provide that an applicant can overcome a cited reference by demonstrating conception of the claimed subject matter prior to the effective date of the cited reference coupled with due diligence from prior to the effective date to a subsequent reduction practice. In particular, 35 U.S.C. § 102(a) states that a person is entitled to a patent unless "the

invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, **before the invention thereof by the applicant**..." The M.P.E.P. states that "A rejection based on 35 U.S.C. 102(a) can be overcome by:... **Filing an affidavit or declaration under 37 CFR 1.131 showing prior invention**...." *See* M.P.E.P. § 706.02 (b). As set forth in 37 C.F.R. § 1.131, a patent applicant "may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based." *See also*, M.P.E.P. § 715. "The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of the invention in this country ... **at least conception being at a date prior to the effective date of the reference**." *See* M.P.E.P. § 715.07. The showing of facts must be sufficient to show "**conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice.**" *See id.*

Likewise, the M.P.E.P. states that "A rejection based on 35 U.S.C. 102(e) can be overcome by:... **Filing an affidavit or declaration under 37 CFR 1.131 showing prior invention**...." *See* M.P.E.P. § 706.02 (b).

Applicants maintain that, although the earliest priority claim in this application has been amended to be August 24, 2000, the applications to which priority was previously claimed (U.S.Application Serial No. 09/380137 filed 8/25/1999, PCT/US99/12252 filed 6/2/1999, and U.S. Provisional Application 60/088740 filed 6/10/19980), each of which are now abandoned, may be utilized as evidence to prove conception. In particular M.P.E.P. §2138.04 (IV) states:

> An abandoned application with which no subsequent application was copending serves to abandon benefit of the application's filing as a constructive reduction to practice and the abandoned application is evidence only of conception. *In re Costello*, 717 F.2d 1346, 1350, 219 USPQ 389, 392 (Fed. Cir. 1983).

U.S. Provisional Application Serial No. 60/088740 discloses the polypeptide of SEQ ID NO: 50 (PRO1069) and discusses its homology to channel inducing factor. The uses provided for the polypeptide include the preparation of antibodies which recognize the PRO1069 polypeptide. (See U.S. Provisional Application Serial No. 60/088740 page 26, line 3-page 31,

line 10 and Example 7). The specification also describes the use of the antibodies in diagnostic assays. (See U.S. Provisional Application Serial No. 60/088740 page 31, lines 12-25). Applicants maintain that this disclosure is sufficient to demonstrate conception and utility prior to the effective dates of the Lal and Walker references.

II. The Caselaw Cited by the Examiner is not Relevant to the Present Situation

Applicants maintain that the cases cited by the Examiner, *Silvestri v. Grant* and *Bosies v. Benedict*, are not relevant because, in contrast to the present situation, they relate to situations where the applicants did not appreciate that they were in possession of the invention or could not demonstrate that they conceived of the structure of the claimed invention. *Silvestri v. Grant* involved an interference on claims reciting derivatives of ampicillin having a certain infrared spectrograph and possessing greater storage stability than a previous form of the drug. The court indicated that in order to prevail in the interference, Silvestri could not merely demonstrate that he had prepared the compounds prior to Grant. Rather, Silvestri was required to demonstrate that he appreciated that he had made the recited form of ampicillin. Thus, an accidental or unappreciated preparation of the ampicillin derivative was insufficient. (See also *Invitrogen Corporation v. Clontech Laboratories, Inc.*, 77 USPQ2d 1161 (Fed. Cir. 2005) finding that one has not conceived of a composition where one does not realize that one has prepared the composition).

In contrast to the issue in *Silvestri v. Grant*, Applicants had determined the sequence of the polypeptide of SEQ ID NO: 50 as of the June 10, 1998 filing date of U.S. Provisional Application Serial No. 60/088740. In addition, as discussed above, U.S. Provisional Application Serial No. 60/088740 discloses how to make antibodies which bind to the polypeptide of SEQ ID NO: 50. Accordingly, unlike the applicants in *Silvestri v. Grant* the Applicants in the present application were aware that they possessed the claimed antibodies as of June 10, 1998.

Likewise *Bosies v. Benedict* is not applicable to the present situation. In *Bosies v. Benedict*, the issue was whether laboratory notebook entry containing a generic chemical formula specifying that a particular alkyl chain was "n" carbons in length without providing a definition for "n" was sufficient to establish conception of compounds in which n was 2-8. The court found

that there was insufficient evidence to establish that Benedict intended "n" to refer to alkyl chains of 2-8 carbons in length.

Thus, the issue in *Bosies v. Benedict*, like that in *Silvestri v. Grant* involved whether the applicant appreciated the structure of the claimed compounds. Again, in the present situation, Applicants had determined the sequence of the polypeptide of SEQ ID NO: 50 as of the June 10, 1998 filing date of U.S. Provisional Application Serial No. 60/088740. In addition, as discussed above, U.S. Provisional Application Serial No. 60/088740 discloses how to make antibodies which bind to the polypeptide of SEQ ID NO: 50. Accordingly, as of June 10, 1998, Applicants were aware that they possessed the claimed antibodies.

For the foregoing reasons, Applicants maintain that the cases cited by the Examiner are not relevant to the present situation.

III. The Experiments of June 13, 2000 are not Necessary to Demonstrate Conception of the Claimed Invention

The Examiner asserts that in order to demonstrate conception of the claimed invention Applicants need to demonstrate the differential expression of the PRO1069 mRNA. As discussed above, Applicants maintain that the disclosure in U.S. Provisional Application Serial No. 60/088740 is sufficient to establish utility of the claimed invention. However, even if the differential expression data were necessary to establish the utility of the claimed invention, Applicants maintain that establishing the utility of the claimed invention is not required to prove conception. Rather, demonstration of utility is part of reduction to practice.

In *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 32 USPQ2d 1915 (Fed. Cir. 1994) the Court of Appeals for the Federal Circuit considered whether conception of claims related to the AIDS drug AZT required Burroughs Wellcome to demonstrate that AZT was effective in a T cell model for HIV replication or whether the determination of the structure of AZT coupled with experiments using murine virues rather than HIV itself was sufficient. The court stated:

> But an inventor need not know that his invention will work for conception to be complete. *Applegate v. Scherer*, 332 F.2d 571, 573, 141 USPQ 796, 799 (CCPA 1964). He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice. *Id.*, *see also Oka v. Youssefyeh*, 849 F.2d 581, 584, n. 1, 7 USPQ2d 1169, 1171 n. 1 (Fed. Cir. 1988).

In *Oka v. Youssefyeh*, 7 USPQ2d 1171 (Fed. Cir. 1998), the court evaluated whether a laboratory notebook entry containing a generic chemical formula was sufficient to establish conception of the claimed compounds in view of evidence showing that the applicants were not in possession of an operative method of making the claimed compounds. The court noted:

> In view of our determination respecting conception, we need not and do not reach the parties' arguments on diligence and reduction to practice, except to note that neither party argues that the dual requirement for conception of an operative invention (idea plus method of making) equates conception with reduction to practice. The latter in this case would involve verification of the compound's utility as a hypotensive agent. *Oka v. Youssefyeh*, 849 F.2d 581, 584, n. 1, 7 USPQ2d 1169, 1171 n. 1 (Fed. Cir. 1988)

Applicants are aware of the decisions in *Hitzeman v. Rutter*, 58 USPQ2d 1161 (Fed. Cir. 2001), *In re Moore*, 170 USPQ 260 (CCPA 1971) and *In re Stempel*, 113 USPQ 177 (CCPA 1957). However, Applicants maintain that these decisions are not relevant to the present situation.

In *Hitzeman v. Rutter* the court considered whether the applicants in an interference conceived of claims to genetically modified yeast strains which produced Hepatitis B Surface Antigen having a particular size and sedimentation rate where the applicants had constructed such a strain prior to the relevant date but had not demonstrated that the yeast actually produced the particles prior to that date. In finding that the applicants were not able to demonstrate conception, the court distinguished the facts in *Burroughs Wellcome Co. v. Barr Laboratories, Inc.* on the basis that in *Hitzeman* the issue was whether the inventors "had a reasonable expectation of producing the claimed device or composition." Unlike the situation in *Hitzeman*, in view of the present Applicants' determination of the sequence of the PRO1069 polypeptide and the polynucleotide encoding it, the Applicants in the present application had a reasonable expectation of producing the claimed antibodies prior to the June 10, 1998 filing date of U.S. Provisional Application Serial No. 60/088740. Thus, the present situation is analogous to the facts in *Burroughs Wellcome* and distinguishable from the facts in *Hitzeman.* Accordingly, as discussed above, Applicants maintain that the disclosure in U.S. Provisional Application Serial No. 60/088740 is sufficient to demonstrate conception of the claimed invention.

Both *In re Moore* and *In re Stempel* related to situations where the Applicants had not demonstrated utility for the claimed invention as of their alleged conception dates. In both cases,

the applicants submitted a Declaration under 37 C.F.R. 1.131 to swear behind references which disclosed the claimed inventions but did not provide a utility for them. In both decisions the court found the 1.131 Declaration sufficient to overcome the cited references. Although there were statements in these decisions suggesting that the Applicants would have had to establish utility of the claimed invention as of their asserted conception dates if the cited references had disclosed the utility of the claimed inventions, these statements are essentially dicta since the references involved in these decisions did not disclose utilities for the claimed inventions.

Applicants maintain that the *Burroughs* and *Oka* cases cited above, which were decided after *In re Moore* and *In re Stempel*, clearly establish that demonstration of utility is part of reduction to practice rather than conception. Accordingly, Applicants maintain that the Declaration Under 35 U.S.C. 1.131 submitted submitted October 11, 2005 establishes conception of the claimed invention prior to June 10, 1998 coupled with diligent reduction to practice. Since June 10, 1998 is prior to the effective dates of the Lal and Walker references, Applicants maintain that the Declaration Under 35 U.S.C. 1.131 submitted submitted October 11, 2005 is sufficient to overcome the Lal and Walker references.

For the foregoing reasons, Applicants respectfully request that the rejections based on Lal and Walker be withdrawn.

**Rejection under 35 U.S.C. § 103 – Obviousness**

Claims 1-5 were rejected under 35 U.S.C. 103(a) on the assertion that they are unpatentable over Walker et al. (U.S. Patent 6,277,57481, 4/9/1999) in view of Queen et al. (U.S. Patent 5,530,101, issued 6/96).

As discussed above, Applicants have demonstrated conception of the claimed invention prior to the April 9, 1999 date which the PTO asserts for the Walker reference, together with diligence in reducing the invention to practice. Thus, Walker is not available as prior art. Applicants further maintain that the disclosure of humanized antibodies in Queen does not render the claimed antibodies obvious because there is no teaching or suggestion of antibodies which bind to the polypeptide of SEQ ID NO: 50 in Queen. Applicants therefore respectfully request that the rejection of the claims under 35 U.S.C. § 103 be withdrawn.

## CONCLUSION

In view of the above, Applicants respectfully maintain that claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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